



Pharmaceutical Quality Assurance: Scenario, Need, and Career

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Quality assurance (QA) is a wide-ranging concept to ensure the quality of drug ingredient or drug product meets not only desired specification of product quality but also ensures that the drug ingredient or product is manufactured following set of current good manufacturing practices as per current regulatory norms of World Health Organization (WHO) and Food and Drug Administration (FDA).

In early 1990, especially in developing countries, there was no concept like QA in the industry engaged in manufacturing of pharmaceutical drug ingredients or drug products neither it was a requirement by set regulations of WHO and local FDA. During that time, the concept of QA was in wide use in aeronautical and automation industries to meet product quality with zero defects and high productivity.

The thalidomide disaster is one of the darkest episodes in pharmaceutical research history. The drug was marketed as a mild sleeping pill safe even for pregnant women. However, it caused thousands of babies worldwide to be born with malformed limbs. The damage was revealed in 1962.

After thalidomide disaster, the regulation in pharmaceutical industries has developed like anything and many sets of new regulation have been enforced by various governing bodies throughout the globe which were inclusive of requirement and adoption of QA system in the pharmaceutical industry. The WHO, Geneva has introduced a guideline for, "QA of pharmaceuticals", a compendial of guideline and related material volume-2, good manufacturing practice and inspection in the year 1999.

Over a period of the last many decades, regulatory guidelines and regulators have continuously added new values to the concepts by adopting more advanced methodology and tools of the same. However like any regulation, during the early days, it was quite hard for industries to digest and implement

the requirements of QAs but the industry has come up with this challenge over a period of time. The concept of QA is not only helped the industry to develop an overall control on the quality aspect of the pharmaceutical drug ingredients or drug products from stage of the drug design to drug discontinuation but also poured a lot of confidence to avoid data integrity issues and handling of quality failures. The stringent, scientific, systematic and sustainable approach of QA to commercial drug production ensures the protection of public health. QA in the pharmaceutical industry has also added a lot of value to track and trace the information about the drug ingredient and/or drug product manufacturing from the purchase of raw material to the expiry of the drug ingredient and/or drug product through the electronic and manual data management system.

With an increase in regulatory requirements for assuring all dimensions of pharmaceutical drug ingredients or drug products manufacturing, the employment rate in the same sector is increased like anything. There are about 10,500 pharmaceutical manufacturing units and over 3000 companies in India. India is engaged in the export of various dosages of drugs as well as bulk drugs. India is the fourth-largest producer of medicines in the world and is also a large exporter of medicines. India Pharma industry is in its best dimension for growth and its growth rate at a compound annual rate (CAGR) of more than 15% in the last 5 years. Looking forward to the growth of the pharmaceutical industry and the golden future of the Indian Pharma industry in the globe and increasing regulatory requirements and expectation of regulators for implementation of an effective QA system, it is highly likely to have an obvious hike in the hiring rate for pharmaceutical QA profiles. It is expected that the career in pharmaceutical QA will make one shine due to dynamic work profile and good pay scale.